

**What is Claimed is:**

1           1. An orally administered pharmaceutical composition  
2 comprising cyclosporine, ethanol, polyoxyethylene glycerol trioleate, and an oil  
3 component.

1           2. The pharmaceutical composition of claim 1, wherein said  
2 cyclosporine is cyclosporine A.

1           3. The pharmaceutical composition of claim 1, wherein said  
2 cyclosporine is present at a concentration from about 5 to about 20% by weight.

1           4. The pharmaceutical composition of claim 3, wherein said  
2 cyclosporine is present at a concentration from about 8 to about 12% by weight.

1           5. The pharmaceutical composition of claim 3, wherein said  
2 cyclosporine is present at a concentration of 10% by weight.

1           6. The pharmaceutical composition of claim 1, wherein said oil  
2 component is ethyl oleate.

1           7. The pharmaceutical composition of claim 1, wherein said  
2 ethanol is present at about 15 to about 40 v/v%.

1           8. The pharmaceutical composition of claim 7, wherein said  
2 ethanol is present at about 15 to about 25 v/v%.

1           9. The pharmaceutical composition of claim 7, wherein said  
2 ethanol is present at 20 v/v%.

1           10. The pharmaceutical composition of claim 1, wherein said  
2 polyoxyethylene glycerol trioleate is present at about 20 to about 50 v/v%.

- 9 -

1           11. The pharmaceutical composition of claim 1, wherein said oil  
2 component is present at about 40 to about 65 v/v%.

1           12. The pharmaceutical composition of claim 11, wherein said oil  
2 component is present at about 55 to about 65 v/v%.

1           13. The pharmaceutical composition of claim 11, wherein said oil  
2 component is present at 60 v/v%.

1           14. An orally administered pharmaceutical composition  
2 comprising cyclosporine, ethanol, polyoxyethylene glycerol trioleate and ethyl  
3 oleate in a weight ratio of cyclosporine, pure ethanol, polyoxyethylene glycerol  
4 trioleate and ethyl oleate of about 5:18:25.9:50.1 to about 15:16:23.1:44.9.

1           15. The pharmaceutical composition of claim 14, wherein the  
2 weight ratio of cyclosporine, pure ethanol, polyoxyethylene glycerol trioleate and  
3 ethyl oleate is 10:17.1:24.5:47.5.

1           16. The pharmaceutical composition of claim 15, wherein said  
2 composition upon dilution with an aqueous media at a ratio of 1 part composition to  
3 100 parts aqueous media forms a spontaneous emulsion.

1           17. The pharmaceutical composition of claim 16, wherein said  
2 spontaneous emulsion comprises particles having a diameter of 50 to 185 nm.

1           18. A method of preparing an orally administered pharmaceutical  
2 composition comprising the steps of:

3           dissolving cyclosporine in ethanol to form a solution;

4           combining polyoxyethylene glycerol trioleate and an oil  
5 component with the solution to form a mixture; and

- 10 -

6                   diluting the mixture with an aqueous media to allow formation  
7                   of a spontaneous emulsion.

1                 19. The method of claim 18, further comprising the step of gently  
2                 mixing the diluted mixture to disperse the emulsion.

1                 20. The method of claim 18, wherein the step of diluting further  
2                 comprises diluting 1 part of the mixture with 100 parts of aqueous media.

1                 21. The method of claim 18, wherein said oil component is ethyl  
2                 oleate.

1                 22. The method of claim 18, wherein said cyclosporine is  
2                 cyclosporine A.

1                 23. The method of claim 18, wherein the cyclosporine is present at  
2                 a concentration of 10% by weight

1                 24. The method of claim 18, wherein said ethanol is present at  
2                 about 15 to about 40 v/v%.

1                 25. The method of claim 18, wherein said polyoxyethylene  
2                 glycerol trioleate is present at about 20 to about 50 v/v%.

1                 26. The method of claim 18, wherein said oil component is present  
2                 at about 40 to about 65 v/v%.

1                 27. The method of claim 18, wherein said composition comprises  
2                 cyclosporine, ethanol, polyoxyethylene glycerol trioleate and ethyl oleate in a  
3                 weight ratio of cyclosporine, pure ethanol, polyoxyethylene glycerol trioleate and  
4                 ethyl oleate of 10:17.1:24.5:47.5.

- 11 -

1           28. The method of claim 27, wherein said spontaneous emulsion  
2 comprises particles having a diameter of 50 to 185 nm.

1           29. The method of claim 28, wherein said spontaneous emulsion  
2 comprises particles having a diameter of 50 to 150 nm.

1           30. The method of claim 17, wherein said spontaneous emulsion  
2 comprises particles having a diameter of 50 to 150 nm.

2025 RELEASE UNDER E.O. 14176